UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,983	06/26/2001	Dinesh O. Shah	6821.US.01	9651

7590 10/02/2002

Steven F. Weinstock
ABBOTT LABORATORIES
D-377/AP6D-2
100 Abbott Park Road
Abbott Park, IL 60064-3500

EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/02/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/891,983	SHAH ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8,12,13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election of Group I, claims 1-17 and 22 with traverse in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 18-21 are withdrawn from consideration as drawn to non-elected inventions. Claims 1-17 and 22 are under examination.

This application remains in incomplete compliance with the sequence rules. In particular, Table I at page 19 lists numerous amino acid sequences that are not accompanied by SEQ ID NO's as is required (see 37 CFR 1.821(d). The time period for complying with this aspect of the sequence rules is the same as for replying to this Office action.

The disclosure is objected to because of the following informalities:

The deposit information at page 15 is incomplete.

Appropriate correction is required.

Claims 1 and 10 are objected to because of the following informalities:

In claim 1, line 1, "simultaneously" is misspelled.

In claim 10, line 4, it appears that "14-1287-25" should be "14-1287-252."

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because step a)1) recites contacting a test sample with "at least one HCV viral antigen ... coated on a solid phase" but step b), the first appearing "detecting" step, recites "presence of said complexes indicating presence of HCV antigen", while step a)2) recites contacting a test sample with "at least one antibody to HCV ... coated on said solid phase" and step c), the second appearing "detecting" step, recites "presence of said complexes indicating presence of HCV antibody." It would appear that the presence of the antibody/antigen complexes formed at step a)1) would indicate the presence of HCV antibody and the presence of the antigen/antibody complexes formed at step a)2) would indicate the presence of HCV antigen in the test sample. Applicant is requested to review the claim and to clarify the language as necessary.

Claim 2 is indefinite in reciting "and portions thereof" since claim 1, from which claim 2 depends, recites "or portion thereof." It is not clear what is intended by two recitations of "portion(s) thereof," i.e., a portion of a portion.

Claim 9 is indefinite, similarly to claim 2, in reciting "and portions thereof" and being dependent from claim 8.

Claim 8 is indefinite because the preamble recites "A method for simultaneously detecting the presence of at least one HCV antigen and at least one HCV antibody ..." but the correlating language, "presence of said signal indicating presence of at least one

antigen ... selected from the group consisting of HCV antigen and HCV antibody," does not correspond to the preamble.

Claim 10 is indefinite because it recites a Markush group but recites the word "and" twice, once at line 7 and again in the last line. It is suggested that "and" be deleted from line 7.

Claim 17 is confusing since it recites "A method of detecting at least one HCV antigen" and requires an HCV antibody coated on a solid phase, and contacting with a test sample, and adding a labeled conjugate that binds to the bound antibody. It is not understood how this assay format will indicate the presence of an antigen in the test sample, since it would appear that labeled conjugate will always bind to bound antibody, regardless of whether or not antigen is present in the test sample. It is possible that necessary process steps have been omitted, or that the conjugate specifically binds to bound antigen rather than to bound antibody.

Claim 22 is indefinite and incomplete in reciting "An immunoassay," which is interpreted to be a process claim, without any active process steps.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is evident that monoclonal antibodies 13-959-270, 14-

1269-281, 14-1287-252, 14-153-234, 14-153-462, 14-1705-225, 14-1708-269, 14-1708-403, 14-178-125, 14-188-104, 14-283-112, 14-635-225, 14-726-217, 14-886-216, 14-947-104, 14-945-218, 13-975-157, 14-1350-210, 107-35-54, 110-81-17, C11-3, C11-7, C11-10, C11-14 and C11-15 are all required in order to practice the claimed invention since each is specifically recited. Applicant must either comply with the biological deposit rules as set out in 37 CFR 1.801 - 1.809 or demonstrate that each antibody is well-known and readily available to the public. Every member of a Markush group must be enabled.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 22 is rejected under 35 U.S.C. 102(a) as being anticipated by Dawson et al. (Transfusion 40, No. 10S:83S, Abstract SP 161, October 2000) cited on PTO 1449. Dawson et al. disclose co-detection of HCV antibodies and antigens, thus anticipating the subject matter of claim 22.

Claims 16, 17, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,383,740 to Collins. Collins discloses methods for simultaneously detecting antigen and antibody, i.e., both members of a binding pair, where the binding pair members are hepatitis C antigen and hepatitis C antibody, and where an HCV antibody is coated on a solid phase, and where the HCV antigen and HCV antibody to be detected are in an immune complex. See, e.g., Figs. 1 and 2.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Masalova et al. Masalova discloses a method of detecting HCV core antigen in a sample, both recombinant core antigen and natural core protein in donor plasma, comprising contacting the sample with an HCV monoclonal antibody for HCV core antigen that is coated on a solid phase and detecting the presence of antibody/antigen complexes, thus anticipating the subject matter of claim 16. See, e.g., Masalova, page 3, "EIA Sandwich Variant for the Detection of HCV Core Antigen."

Claims 1, 2, 16, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Jolivet-Reynaud et al. (Journal of Medical Virology 56:300-309, 1998), cited on PTO 892, attached. Jolivet-Reynaud et al. disclose the detection of both HCV core antigen using a sandwich immunoassay with two murine anti-HCV antibodies and HCV core antibodies using synthetic HCV core peptides coated on a solid phase (see, e.g., page 303, "HCV Core detection in Viremic Sera").

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al., Transfusion, October 2000, cited above, in view of Masalova et al., also cited above. Dawson discloses co-detection of HCV core antigen and HCV antibodies in a chemiluminescent assay but do not specifically disclose a solid-phase immunoassay format, the use of HCV core monoclonal antibodies, or kits. Masalova et al. disclose the use of a solid-phase immunoassay format, sandwich immunoassays, and HCV core monoclonal antibodies. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the conventional solid-phase format, sandwich assays, and HCV core monoclonal antibodies of Masalova in the co-detection assays of Dawson because Masalova teaches the successful use of such assay formats and monoclonal antibodies for the detection of HCV core antigen early after HCV infection. While neither Dawson nor Masalova specifically disclose kits, it would have been obvious to one of ordinary skill in the art at the time the invention was

made to package components to be used together in the form of a kit for reasons of convenience and economy; such components are necessarily kept in containers.

Claims 3-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,627,026 to O'Connor et al. in view of Jolivet-Reynaud et al., cited above. O'Connor et al. teaches the simultaneous detection of antigen and antibody, including hepatitis antigen and antibody, in a sample, and the packaging of the components in the form of a kit (see, e.g., col. 2, lines 58-59) O'Connor does not specifically teach hepatitis C antigen and hepatitis C antibody. Jolivet-Reynaud et al. teach the detection of both HCV core antigen using a sandwich immunoassay with two murine anti-HCV antibodies and HCV core antibodies using synthetic HCV core peptides coated on a solid phase, and point out that the S42G peptide detected human anti-core antibodies, while the murine monoclonal antibodies used detected two non-overlapping epitopes that are different from the major human epitopes on HCV core protein. Neither O'Connor nor Jolivet-Reynaud specifically teach use of a conjugate comprising an antibody attached to chemiluminescent compound. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the combination hepatitis C antigen and hepatitis C antibody assay format of Jolivet-Reynaud in the simultaneous hepatitis antigen-antibody detection of O'Connor et al. because Jolivet-Reynaud teach an assay for both hepatitis C antigen and hepatitis C antibody, and because O'Connor teach the desirability of simultaneous hepatitis antigen-antibody detection for screening of blood intended for transfusion, e.g. Use of a chemiluminescent label in place of the avidin-biotin system or the enzyme label of

O'Connor or of Jolivet-Reynaud would have been obvious since all are conventional labeling systems, as pointed out in the instant specification.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kashiwakuma et al. disclose the detection of HCV core protein in patient sera by immunoassay using anti-core monoclonal antibodies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
September 29, 2002